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10/667,043

09/22/2003

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EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/667,043	<b>Applicant(s)</b> ESKURI, ALAN	
	<b>Examiner</b> HELEN NGUYEN	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 13-16, 19, 22-24, 26 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 11, 13-16, 19, 22-24, 26 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This Office Action is responsive to the Advisory Action dated 1/9/2009. In light of Applicant's After Final Remarks dated 12/17/2008, the previous Final Rejection is withdrawn and replaced with the following responsive. **Claims 1-4, 8- 9, 11, 13-16, 19, 22-24, 26, and 30** remain under prosecution.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2 and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou (US Pub No. 20020183654).

4. In regards to **Claim 1**, Zhou discloses a guide wire 100 comprising:

an elongated inner core member 106 including a proximal section 102 and a distal section 104, the distal section including a proximal portion 136 and a distal portion 140, best seen in Figure 1-2;

an elongated reinforcing member 128 having a proximal end 144 and a distal end 146, the elongated reinforcing member disposed about the proximal portion of the distal section such that the distal portion of the distal section is free of the reinforcing member, best seen in Figure 2;

Art Unit: 3736

an outer coil member 122 having a proximal end and a distal end, the outer coil member disposed about the distal section of the core member, there being no intervening layer of material between the distal portion of the distal section of the inner core member and the outer coil member, best seen in Figure 2;

the outer coil member is located exterior of the elongated reinforcing member such that there exists an unoccupied space between the entire perimeter of the elongated reinforcing member and the outer coil member, best seen in Figure 2;

wherein the proximal end of the outer coil member is located proximal of the proximal end of the elongated reinforcing member, best seen in Figure 2.

5. In regards to **Claim 2**, Zhou discloses the reinforcing member 128 comprises a nickel-titanium alloy (¶0021).

6. In regards to **Claim 11**, Zhou discloses the outer coil member 122 comprises stainless steel (¶0022).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

8. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou in view of O'Connor et al (US Pat No. 6887235).

9. Zhou discloses the invention above but does not expressly disclose that the reinforcing member is a tube having at least one cut or groove or is made of a nickel-titanium alloy. It is noted that Zhou teaches said reinforcing member as tubular (¶0019), also see Figure 6-7.

O'Connor et al teach a reinforcing member with a helical groove (40 in figure 3A) or a plurality of cuts (44, 46 in figure 4A) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a nickel-titanium alloy tube having at least one helical groove as taught by O'Connor et al as a reinforcing member in Zhou in order to provide a reinforcing member with desired torque and flexibility characteristics without requiring additional components.

10. **Claims 8-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou in view of Palermo et al (US Pat No. 5769796).

11. In regards to **Claim 8**, Zhou discloses the invention above but does not explicitly disclose the distal portion of the distal section of the core member has a non-circular cross section.

Palermo et al teach an analogous guide wire with a distal portion of the distal section of the core member having a non-circular cross-section (column 6, lines 63-67) as an effective construction of the distal portion. Therefore, it would have been obvious to one of ordinary skill in the art at

Art Unit: 3736

the time the invention was made to modify the distal portion of the core member of Zhou to have a non-circular cross section as taught by Palermo et al as an effective configuration for the guide wire with maintained the characteristic desired for its use.

12. In regards to **Claim 9**, Zhou discloses the invention above but does not explicitly disclose the core member comprises stainless steel. Palermo et al teach an analogous guide wire with a core member comprising stainless steel as an effective material for its construction (Col.7: 14-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the core member of Zhou out of stainless steel as taught by Palermo et al as an effective material for the construction of guide wires having the desired characteristics for its use.

13. **Claims 13-16, 19, 22-24, 26, and 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou in view of Palermo et al, further in view of O'Connor et al.

14. In regards to **Claims 13-14, 19, and 23**, Zhou discloses a guide wire 100 comprising:

an elongated inner core member 106 the core member having a proximal region 102 and a distal region 104, best seen in Figure 1, the distal region having a proximal section 136 and a distal section 140, best seen in Figure 2;

an elongated tubular reinforcing member 128 including nickel-titanium (¶0021) disposed about the inner core member, the reinforcing member having a proximal end 144 and a distal end

Art Unit: 3736

146, wherein the distal end terminates proximal of the distal section of the distal region of the core member, best seen in Figure 2;

an outer coil member 122 having a proximal end and a distal end, the outer coil member disposed over the distal section of the core member and at least a portion of the reinforcing member, best seen in Figure 2;

the outer coil member located exterior of the elongated reinforcing member such that there exists an unoccupied space between the entire perimeter of the elongated reinforcing member and the outer coil member, best seen in Figure 2;

wherein the proximal end of the outer coil member is located proximal of the proximal end of the reinforcing member, best seen in Figure 2.

15. However, Zhou does not disclose the distal region of the core member made of stainless steel. Palermo et al teach an analogous guide wire with a core member comprising stainless steel as an effective material for its construction (Col.7: 14-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the core member of Zhou out of stainless steel as taught by Palermo et al as an effective material for the construction of guide wires having the desired characteristics for its use.

16. However, Zhou and Palermo et al do not disclose the elongated tubular reinforcing member having at least one cut or groove. O'Connor et al teach a reinforcing member with a helical groove (40 in figure 3A) or a plurality of cuts (44, 46 in figure 4A) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a nickel-titanium alloy

Art Unit: 3736

tube having at least one helical groove as taught by O'Connor et al as the reinforcing member in Zhou as modified by Palermo et al in order to provide a reinforcing member with desired torque and flexibility characteristics without requiring additional components while still performing its desired function.

17. In regards to **Claim 16**, Zhou discloses the outer coil member 122 comprises stainless steel (¶0022).

18. In regard to **Claims 15, 22, 26, and 30**, Zhou discloses a guide wire 100 comprising:  
an elongated inner core member 106, the inner core member including a proximal portion 102 having a first cross-sectional area, an intermediate portion 138 having a second cross-sectional area, wherein the second cross-sectional area is less than the first cross-sectional area, and a distal portion 140 having a ribbon profile, best seen in Figure 1-2;

an elongated tubular member 128 including a nickel-titanium alloy (¶0021), the tubular member having a proximal end 144 and a distal end 146, the tubular member being disposed about the intermediate portion of the inner core member, best seen in Figure 2;

a coil tip 122 including stainless steel (¶0022), the coil tip having a proximal end and a distal end, the coil tip extending over the distal portion of the inner core member and the tubular member, best seen in Figure 2;

the coil tip has an outside diameter, wherein the outside diameter of the coil tip is substantially equal to the diameter of the proximal portion of the core member configured to create a smooth transition from the core member to the coil tip, best seen in Figure 1-2.



Art Unit: 3736

19. However, Zhou does not disclose the core member made of stainless steel. Palermo et al teach an analogous guide wire with a core member comprising stainless steel as an effective material for its construction (Col.7: 14-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the core member of Zhou out of stainless steel as taught by Palermo et al as an effective material for the construction of guide wires having the desired characteristics for its use.

20. However, Zhou and Palermo et al do not explicitly disclose the elongated tubular member having at least one cut or groove. O'Connor et al teach a reinforcing member with a helical groove (40 in figure 3A) or a plurality of cuts (44, 46 in figure 4A) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a nickel-titanium alloy tube having at least one helical groove as taught by O'Connor et al as the tubular member in Zhou as modified by Palermo et al in order to provide a reinforcing member with desired torque and flexibility characteristics without requiring additional components while still performing its desired function.

21. In regards to **Claim 24**, Zhou discloses the proximal portion 102 of the core member 106 has a diameter and the intermediate portion 138 has a diameter less than the diameter of the proximal portion, best seen in Figure 1-2.

Art Unit: 3736

***Response to Arguments***

22. Applicant's arguments with respect to claims 1-4, 8-9, 11, 13-16, 19, 22-24, 26, and 30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736